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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/653,267 | 08/31/2000 | Meir Eini | 00/20309 | 4053 |

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12/17/2002

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/17/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,267

Applicant(s)

EINI ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-26,29-37 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) 6,13-25,31,42 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-12,26,29,30,32-37,40,41 and 43-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 6,13-25,31,42 and 52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08/31/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vatter et al (6,224,888).

Vatter teaches cosmetic compositions comprising from about 0 to 90% by weight of a solidifying agent, from about 0 to 90% by weight of an emollient component, from about 0 to 40% by weight of a polar solvent and from about 0.01 to about 50% by weight of vitamin B3 compound, thus meeting instant claims 1, 26 and 37 (see abstract). The emollients of Vatter meet the hydrophobic solvent of the instant claims.

The suitable solvents include flavor oils such as peppermint oil, orange oil and citrus oil. Oils act as emollients and also impart viscosity, tackiness, and drag properties to cosmetic compositions such as lipstick. Examples of suitable oils include hydrogenated vegetable oils, castor oil, palm kernel oil, rapeseed oil, safflower oil, jojoba oil, avocado oil, evening primrose oil, etc, thus meeting claims 4-5, 29-30, 40-41 (col. 5, lines 1-19; col. 6, lines 18-55; col. 12, lines 50-61).

Vatter describes the solidifying agents as being effective in solidifying the particular liquid base materials to be used in cosmetic compositions. The term "solidify" refers to physical and/or chemical alteration of the liquid base material so as to form a solid or semi-solid at ambient conditions, thus rendering instant claim 3 obvious. The

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solidifying agent is preferably present at a concentration of from about 0 to about 90%, more preferably from about 5 to about 40%. **Suitable wax-like solidifying agents include fatty acids, fatty alcohols, fatty acid esters having fatty chains of from about 8 to about 30 carbon atoms.** Preferred wax-like materials include cetyl alcohol, palmitic acid, stearyl alcohol, and mixtures thereof. Solidifying agents also include higher fatty acids, i.e. acids having from 12 to 22 carbon atoms. In the gel sticks the suitable solidifying agents are sodium and potassium salts of higher fatty acids, sodium stearate, sodium palmitate, aluminium stearate, etc. thus meeting instant claims 1, 7-12, 29, 32-37 and 43-48 (col. 8, line 11 through col. 10, line 19).

Vatter also teaches that the solidifying agent in combination with the emollient is believed to act as an occlusive on the skin by forming continuous or discontinuous bi-layer or multi-layer films on the skin (col. 10, lines 47-55).

Vatter discloses some optional ingredients suitable for the composition such as anti-inflammatory agents such as hydrocortisone, and other skin active agents such as vitamin D, retinoic acid, zinc oxide etc (col. 12, lines 19-49).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of Vatter by selecting suitable oil emollients and amounts as disclosed, because of the expectations of successfully producing a cosmetic carrier suitable for active ingredients. Further, one would have been motivated to select emollient oils from renewable sources, such as the disclosed vegetable oils for environmental and marketing reasons.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vatter et al as applied to claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 above, and further in view of Geria (4,992,478).

Vatter, discussed above, lacks specific teachings on psoriasis and dermatitis.

Geria teaches anti-inflammatory skin moisturizing composition, comprising an oil phase, an aqueous phase and an effective amount of a topical medicament. The medicament useful in the present invention may be selected from a wide range of compounds such as antiinflammatories, antibiotics, antifungals and compounds for the treatment of psoriasis, dermatitis etc, (col. 7, lines 32-68).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of Vatter by adding the medicaments and the disorders as taught by Geria, with the reasonable expectations of broadening the range of functions for the base composition.

Response to Arguments

Applicant's arguments filed 10/21/02 have been fully considered but they are not persuasive.

Applicant argues that Vatter discloses the use of a solidifying agent to solidify a liquid base material, which do not become a liquid upon application of shear. However Vatter discloses that the formulations can be in the form of mousses, foams, gels, etc,

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which are liquefied upon application of shear. Vatter's formulations contain all the ingredients of the claimed compositions and within the claimed concentration ranges. Therefore a property of such composition would be inherent.

Applicant argues that Vatter discloses a wide range of ingredients and there is no teaching or suggestion of selective within the range of materials and combinations that will result in the claimed carrier properties. However, in a composition claim when the ingredients and their concentration ranges are disclosed in the prior art, the limitations are considered met by the prior art. Also noted that generally optimization of the concentration ranges will support patentability of the subject matter encompassed by the prior art.

Applicant argues that the specific embodiments of the Vatter patent do not describe both the hydrophobic solvent and the solidifying agent in the required concentration range. The specified example was example 12, which applicant believes does not contain the claimed fatty acid or fatty alcohols as solidifying agent. This is not correct. Example 12 contains stearyl heptanate at over 8% by weight, which meets the required range of 1 to 25% of a solidifying agent, and as noted by the applicant about 80% of the hydrophobic solvent.

Applicant argues that the prior art reference teaches salts of fatty acids and that salts of fatty acids possess different properties than their parent acid. While this is acceptable statement, it is noted that Vatter discloses the solidifying agent to be chosen from fatty alcohols, fatty acids, fatty acid esters and fatty acid amides. The examples of

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such solidifying agents listed include both acids and their salts. Therefore the disclosure meets the requirements of the instant claims.

Applicant argues that Vatter does not teach the use of the carrier for pharmaceutical purposes. However, this is incorrect since Vatter clearly discloses addition of other additives for cosmetic and pharmaceutical purposes in the formulation. Column 12, lines 20-44, disclose additives such as anti-inflammatories, germicides, pharmaceutically active ingredients, skin care actives, etc.

Applicant argues that the reference of Geria does not teach an oleaginous pharmaceutical carrier comprising the solidifying agents and the hydrophobic solvents in the required ranges, therefore cannot address the deficiencies of Vatter patent. However, Vatter is shown to teach the said requirements and also the addition of pharmaceutical actives. Geria is merely relied upon to teach the use of anti-inflammatories in treating skin disorders such as psoriasis.

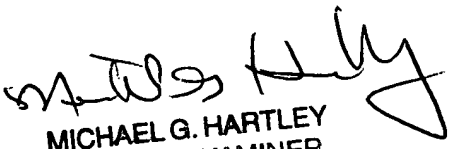
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
December 12, 2002


MICHAEL G. HARTLEY
PRIMARY EXAMINER